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10/657,915	09/09/2003	Kenneth M. Adams	M190.145.101	7670

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EXAMINER
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HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/657,915

Applicant(s)

ADAMS ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-24 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-24 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 17 and 22-23, 31-32 and 36 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) in view of Marino et al. (U.S. Patent No. 6,280,447).

Adams discloses a surgical instrument see FIG. 2 and FIG. 4A-B) comprising an outer tubular member (ref. #18) having a proximal section, an intermediate section, a distal section, and a central lumen (ref. #36) extending from the proximal section to the distal section, the distal section forming a pocket (ref. #65) fluidly connected to the

central lumen, the pocket having a bottom surface and an opposed upper opening; an elevator tip (ref. #68) extending distal the pocket; and an inner tubular (ref. #22) member rotatably received within the central lumen, a distal end of the inner tubular member forming a cutting tip (ref. #150) positioned within the pocket. Upon final assembly, at least a portion of the cutting tip is exposed relative to the outer tubular member via the upper opening of the pocket (functional/intended use recitation). The pocket terminates at a distal-most end. The elevator tip includes an upper surface extending from the distal-most end of the pocket, the upper surface including a proximal region and a distal region, wherein at least a portion of the distal region extends from the proximal region in an angular fashion in longitudinal cross-section. At least a portion of the proximal region of the top surface of the elevator tip extends downwardly from the distal-most end of the pocket. The proximal region is curved in longitudinal cross-section. The elevator tip terminates in a distal end point, and further wherein the distal end point is laterally above the distal-most end of the pocket when the outer tubular member is oriented such that the bottom surface of the pocket is below the upper opening. The pocket is further terminates at a distal-most end point, and further wherein upon final assembly, a distal end of the cutting tip is longitudinally spaced from the distal-most end point. The instrument is adapted for use in a septoplasty procedure (functional/intended use recitation). The elevator tip is selectively axially moveable relative to the cutting tip.

Adams disclose the claimed invention except for specifically defining the cutting tip for resection as a cylindrical burr with cutting protrusions (flutes), and except for the

following ranges and optimum values: the elevator tip distally extending at least 0.05 inch relative to the distal-most end of the pocket, the angular extension of the distal region defining an included angle in the range of 10 degrees-50 degrees relative to a central axis of the outer tubular member, specifically 20 degrees and 40 degrees, the angular extension of the proximal zone defining an included angle in the range of 100 degrees-140 degrees relative to a central axis of the proximal portion, specifically approximately 120 degrees. Also, Adams fails to disclose the specific shape/configuration of the pocket region.

Marino et al. disclose that a cylindrical burr with cutting protrusions can be used as a resection tool to resect bony tissue (see Abstract and col. 1, lines 21-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the cutting tip Marino et al. as a cylindrical burr with cutting protrusions to resect bony tissue.

Regarding claims 2-8 and 11-12, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams and Marino et al. with the elevator tip distally extending at least 0.05 inch relative to the distal-most end of the pocket, the angular extension of the distal region defining an included angle in the range of 10 degrees-50 degrees relative to a central axis of the outer tubular member, specifically 20 degrees and 40 degrees, the angular extension of the proximal zone defining an included angle in the range of 100 degrees-140 degrees relative to a central axis of the proximal portion, specifically approximately 120 degrees, since it has been held that discovering an optimum value of a result

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effective variable involves only routine skill in the art and it has also been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the pocket region of Adams in view of Marino et al. in the specific shape/configuration claimed by Applicant, since it is one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a pocket region. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 15-16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) and Marino et al. (U.S. Patent No. 6,280,447) further in view of Toriumi et al. (U.S. Patent No. 6,214,009).

Adams and Marino et al. disclose the claimed invention except for the bottom surface forms openings fluidly connected to an irrigation source by an irrigation tube extending exteriorly along the outer tubular member and fluidly connected to the openings.

Toriumi discloses a bottom surface that forms openings (ref. #42) fluidly connected to an irrigation source by an irrigation tube (ref. #30) extending exteriorly along the outer tubular member and fluidly connected to the openings to deliver irrigating fluid to the cutting tip (col. 3, lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams and Marino et al. with a bottom surface that forms openings fluidly connected to an irrigation source by an irrigation tube extending exteriorly along the outer tubular member and fluidly connected to the openings further in view of Toriumi to deliver irrigating fluid to the cutting tip.

Claims 18-19 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) and Marino et al. (U.S. Patent No. 6,280,447) further in view of Adams (U.S. Patent No. 6,312,438).

Adams '263 in view of Marino et al. discloses the claimed invention except for an aspiration passage extending through the outer tubular member for aspirating cut tissue and the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member.

Adams '438 discloses an aspiration passage extending through the outer tubular member for aspirating cut tissue and the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member (col. 3, lines 36-46) in order to define a suction passage through the inner member by which debris, such as tissue, blood, and saline, is aspirated.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams '263 and Marino et al. with an

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aspiration passage extending through the outer tubular member for aspirating cut tissue and the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member further in view of Adams '438 in order to define a suction passage through the inner member by which debris, such as tissue, blood, and saline, is aspirated.

Claims 20-21 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) and Marino et al. (U.S. Patent No. 6,280,447) in view of Adams (U.S. Patent No. 6,312,438).

Adams '263 and Marino et al. discloses the claimed invention except for the intermediate section of the outer tubular member defining a longitudinal bend approximately 12 degrees relative to a central axis defined by the proximal section.

Adams '438 discloses the intermediate section of the outer tubular member defining a longitudinal bend approximately 12 degrees relative to a central axis defined by the proximal section (col. 4, lines 65-67) in order to provide access to surgical sites (col. 1, lines 45-50)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams '263 and Marino et al. with the intermediate section of the outer tubular member defining a longitudinal bend approximately 12 degrees relative to a central axis defined by the proximal section in view of Adams '438 in order to provide access to surgical sites.



Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) and Marino et al. (U.S. Patent No. 6,280,447) further in view of West, Jr. (U.S. Patent No. 5,364,395).

Adams and Marino et al. discloses the claimed invention except for an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member.

West, Jr. discloses an intermediate tubular (ref. #92) member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member in order to provide an electrically insulative layer (col. 9, lines 55-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams and Marino et al. with an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member in view of West, Jr. in order to provide an electrically insulative layer.

***Response to Arguments***

Applicant's arguments filed 11/08/2007 have been fully considered but they are not persuasive.

Applicant argues that the specific shape/configuration of the "pocket" is unobvious over Adams '263. Applicant argues that because Adams does not envision the use of a bur cutting tool, it would not be obvious to depart from the singular angular cutting window illustrated in FIG. 3B and 4B of the Adams reference. The examiner respectfully disagrees. It is well known in the art that different tools (e.g. reamers, burs, drills, rasps, etc.) can be interchangeably employed to cut bony tissue; moreover, the fact that Adams does not envision using a bur does not show that it would be unobvious to modify the shape of the pocket. Also, Applicant's arguments with regard to the shape/configuration of the pocket being unobvious over Adams do not overcome the rejections applied thereto since applicant has not provided any convincing showing that the claimed configuration of the pocket is anything more than an optimum shape. Applicant has not provided any showing that such limitations are "critical". *In re Cole*, 140 USPQ 230 (CCPA 1964); *In re Kuhle*, 188 USPQ 7 (CCPA 1975); *In re Davies*, 177 USPQ 381 (CCPA 1973). Mere arguments by counsel cannot take the place of evidence. *In re Cole*, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); *In re Walters*, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al. It is noted that on page 7 of Applicant's specification, it states that "Alternatively, other dimensions and/or configurations of the pocket 48 can also be employed." Thus, it is clear that the claimed configuration of the pocket is not critical to the invention and may be properly rejected

by asserting an obvious change of shape or form using precedent established by prior case law.

The rejections are deemed proper.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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